

**IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION**

UNITED STATES OF AMERICA

v.

CASE NO. 1:19cr00016

**INDIVIOR INC. (a/k/a Reckitt Benckiser
Pharmaceuticals Inc.) and
INDIVIOR PLC**

**REPLY IN SUPPORT OF DEFENDANTS'
MOTION TO COMPEL**

In its Motion to Compel, Indivior simply seeks an order requiring full compliance with *Brady* and Rule 16, and nothing more. This full compliance of course includes the production of all documents and information known to the investigative team that are material to Indivior's preparation of its defense. The government downplays its obligations and contends that selected materials it hand-picked to produce from certain of the relevant government agencies fulfill its obligations entirely. But the government cannot comply with its obligations under *Brady* and Rule 16 by choosing a subset of relevant documents to produce when members of its investigative team know there are substantial additional materials in the possession of these agencies that are material to Indivior's defense and potentially exculpatory. Contrary to the government's assertions in its Response in Opposition to Indivior's Motion to Compel (ECF No. 146) (hereinafter "Gov. Response" or "Response"), all such additional materials must be produced.

ARGUMENT

I. The government must produce all *Brady* and Rule 16 materials known to any member of the investigative team.

The government advances an overly narrow view of its obligations under Rule 16 and *Brady*, focusing entirely on documents *in the possession of* the specific agency offices that actively participated in the investigation of Indivior. But Rule 16 and *Brady* also extend to any defense-favorable material *known* to any member of the investigative team. *See Kyles v. Whitley*, 514 U.S. 419, 437 (1995) (explaining that the government’s obligation includes any favorable documents the prosecution knows exist, as well as “any favorable evidence known to the others acting on the government’s behalf in the case”). Thus, under controlling Supreme Court precedent, it is irrelevant that members of any particular agency or sub-agency possessing material documents did not take an active investigative role in the case.

It is beyond dispute, for example, that the Department of Health and Human Services (“HHS”), is part of the investigative team in this case. *See, e.g.*, Gov. Response at 1-2. Thus, if HHS is aware—and it undoubtedly is—of material documents in the possession of any of its divisions, those documents fall within the government’s *Brady* and Rule 16 obligation to produce, even if the particular division possessing the documents did not play an active role in the investigation. These obligations do not stop at the desks of those particular individuals who ran the investigation directly, and the government cannot build walls within the same agency to shield defense-favorable information that it knows exists. “[T]he prosecution is in a unique position to obtain information known to other agents of the government,” so it “may not be excused from disclosing what it does not know but could have learned.” *Carriger v. Stewart*, 132 F.3d 463, 480 (9th Cir. 1997) (citing *Kyles*, 514 U.S. at 438-40).

This means that the government cannot fulfill its obligations by simply pulling publicly available statements or requesting one specific “file” from these key government agencies. It must inquire into what is known to every member of the investigative team and collect and produce *all* such documents or other items that are exculpatory and/or material to Indivior’s defense. If the government has obtained *some* information or evidence from an agency, it cannot shirk its responsibility to obtain *all* information or evidence in the possession of that agency that would be material to the defense. *See, e.g., United States v. Cerna*, 633 F. Supp. 2d 1053, 1060 (N.D. Cal. 2009) (when the prosecution is making written or verbal requests for records, it must be “even-handed as to the point of inquiry,” meaning that the “prosecutor must ask for *all* information on the same subject, pro and con”); *United States v. W.R. Grace*, 401 F. Supp. 2d 1069, 1082 (D. Mont. 2005) (“The prosecution may not simply ask for information it wants while leaving behind other, potentially exculpatory information within agency files.”); *see also* U.S. Dep’t of Justice, Justice Manual § 9-5.002 (including among the factors to consider in “determining whether to review potentially discoverable information from another federal agency . . . [w]hether the prosecutor has obtained other information and/or evidence from the agency”).

Here, the prosecution team has spent years investigating Indivior, and its members are admittedly familiar with public statements issued by the key agencies that are favorable to Indivior on issues relating to dosing, pediatric exposure, safety, and potential diversion of Suboxone Film. Indeed, the government admits in its Response that it has discussed such information favorable to the defense “in meetings dating back to 2014” with Indivior’s counsel. Gov. Response at 14. But the government has never disclosed the internal discussions, analyses, or documents underlying such favorable statements from relevant agencies. It would be absurd

to assume these agencies simply issued public statements without substantial internal and external communication and analyses. The underlying communications and analyses are critical to Indivior's defense. Without this information, Indivior will be severely hampered, if not derailed completely, in its effort to identify agency documents as trial exhibits and, more importantly, potential trial witnesses employed by the government. *Brady* and its progeny mandate that disclosure of exculpatory material be made in a manner that affords the defendant the opportunity to "make effective use of [the information] at trial." *United States v. Shifflett*, 798 F. Supp. 354, 357 (W.D. Va. 1992). The approach of the prosecution team here, which has entailed the production of some publicly available, final statements of government agencies and essentially nothing more from these key agencies, does not come close to achieving that objective.

II. Each of the agencies identified in Indivior's Motion to Compel has information and documents favorable to the defense that are known to the investigative team.

A. Drug Enforcement Administration ("DEA")

Indivior is clearly entitled to exculpatory information from any DEA monitoring or investigation of the physicians Indivior is apparently accused of aiding and abetting to issue prescriptions in a "careless and clinically unwarranted manner," *see* Indictment ¶ 31 (ECF No. 3). Although the government attempts to downplay the materiality of any such monitoring or investigation, or lack thereof, it is critical to Indivior's defense. The DEA is the agency that by law registers physicians to prescribe opioids and has the authority to monitor the prescribing activity of registered physicians and take action against registered physicians who are prescribing illegally.¹ Any action, or inaction, on the part of the DEA as to these physicians will be critical

¹ *See, e.g.*, 21 C.F.R. 1301.36; 21 U.S.C. § 824(a). "Under the CSA, DEA has the authority to deny, suspend, or revoke a DEA registration upon a finding that the registrant has," among other things, "committed an act which would render the DEA registration inconsistent with the public interest." Drug

evidence reflecting the government's own view of the propriety of the physicians' prescribing practices and any need to intervene. That information is, of course, highly material to the question of whether Indivior—a developer of buprenorphine-containing products that has never been a DEA registrant—had any responsibility vis-à-vis the physicians' prescribing practices.

The government itself acknowledges that “[t]he investigative team has not ignored DEA activities.” Gov. Response at 12. This is undoubtedly at least in part due to the DEA's role in monitoring those in the supply chain who may be suspected of diverting controlled pharmaceuticals. It is inconceivable that no member of the investigative team ever inquired into any DEA records associated with Doctors A-D identified in the Indictment or any other health care providers as to whom the government contends Indivior was aware were issuing prescriptions in a “careless and clinically unwarranted” manner. *See* Indictment ¶¶ 102, 113, 128. Whether the DEA actually ever investigated these physicians—and/or the pharmacies that filled the prescriptions written by the physicians—is not dispositive: if it did, and there was no finding or action taken, that information will show that the agency charged with monitoring such activities did not view the physicians' prescribing practices to be actionable; and if it did not, that too shows a lack of concern regarding the physicians' methods of prescribing. Either answer is material to the preparation of the defense and exculpatory. To suggest, as the government does, that this information is in no way relevant to Indivior's action or inaction with respect to these physicians is misguided.

Enforcement Administration, Practitioner's Manual: An Informational Outline of the Controlled Substances Act, at 11 (2006). Suspension of any registration can be done immediately with the issuance to show cause in any case in which “there is an imminent danger to the public health or safety.” 21 C.F.R. 1301.36(e).

Moreover, while the government states that the DEA played no role in the investigation of Indivior, Gov. Response at 12, it does not address FDA Special Agent Darren Petri's repeated statements in witness interviews that he "received information from a Drug Enforcement Administration (DEA) ROI" suggesting that the witness "had information concerning Reckitt Benckiser (RB) regarding this investigation."² This omission is telling. Indivior has not seen this "ROI," which it concludes is a "Report of Investigation," but the context of Special Agent Petri's statements suggest that the DEA was actively involved in the investigation. In light of this involvement, the government must produce to Indivior not just the DEA documents and information known to others on the investigative team that are material to Indivior's defense, but any *other* information or documents within the DEA's knowledge that meet this standard.

B. Food and Drug Administration ("FDA")

Unlike its claims with respect to the DEA, the government does not dispute the FDA's involvement in the investigation of Indivior, Gov. Response at 2, and it acknowledges its awareness of materials in the possession of the FDA's Center for Drug Evaluation and Research ("CDER") that were subject to production under Rule 16 and *Brady*, *id.* at 13. But the government contends it has fully complied with its Rule 16 and *Brady* obligations with respect to the FDA by requesting a single, non-descript "CDER File." *Id.* In fact, the government's FDA production falls far short of what is required under Rule 16 and *Brady*.

While the government suggests that at some point, it became aware that a "CDER File" contained certain undefined "comments arguably favorable to the defense," *id.*, it clearly knows

² See, e.g., Food and Drug Administration, Office of Criminal Investigations, Memorandum of Interview with Dr. Andrew Skinner (Jan. 21, 2015) (MISC_0018611); Food and Drug Administration, Office of Criminal Investigations, Memorandum of Interview with Dr. Craig Buckles (Jan. 21, 2015) (MISC_0018609).

more. By way of example, it knows that all four of the FDA divisions and offices that assessed the Citizen Petition submitted by Indivior (then known as Reckitt Benckiser Pharmaceuticals, Inc. (“RBPI”)), ultimately agreed that “Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging.”³ The government also knows that during an April 2013 meeting among generic buprenorphine manufacturers, the FDA informed the group that it viewed “the packaging of buprenorphine-containing products as a significant safety issue in regards to pediatric exposure,” and recommended that each of the group’s members voluntarily switch to unit-dose packaging, as Indivior had done, for their buprenorphine-containing products.⁴ But rather than requesting all materials relevant to the FDA’s consideration of the pediatric exposure issue, and its guidance to generic manufacturers on the same issue, the government apparently requested just one specific file, which contained only a small subset of the documents tied to the FDA’s consideration of the Citizen Petition.

The government’s obligation under Rule 16 and *Brady* requires a complete production. In particular, given its place on the investigative team, the government must request from the FDA and produce to the defense *all* documents and information *known to the agency* that are material to Indivior’s defense, which would certainly include any materials underlying the FDA’s consideration of the pediatric exposure issue resulting in the conclusions expressed in the

³ Citizen Petition Response from Food & Drug Admin. Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology (Feb. 14, 2012) (RBP0114_19147715); *see also* Citizen Petition Response from Division of Anesthesia, Analgesia, and Addiction Products (Dec. 6, 2012) (RBP0114_19147735); Citizen Petition Response from Division of Medication Error Prevention and Analysis (Feb. 14, 2013) (RBP0114_19147756-57); Citizen Petition Response from Division of Epidemiology (Feb. 14, 2013) (RBP0114_19147802) (collectively, “Citizen Petition Responses”).

⁴ Buprenorphine Prod. Mfrs. Grp. (BPMG), Meeting Minutes of FDA Call on BTOD REMS Submission 3-5 (Apr. 9, 2013) (RBP0114_19147639).

Citizen Petition Responses noted above and related guidance to generic manufacturers. *See Kyles*, 514 U.S. at 437 (including in the category of materials the government must produce to the defense “any favorable evidence known to the others acting on the government’s behalf in the case”). This latter category of materials will include, though not be limited to, email communications and other correspondence regarding the buprenorphine packaging issue before and after the FDA issued its decision on the Citizen Petition, records of related phone calls, communications with the DEA, and records of additional communications with buprenorphine manufacturers. Given the FDA’s position on pediatric exposure, these materials underlying the agency’s consideration of the issue will directly undermine the government’s claims that Indivior made false statements that Suboxone Film was safer and less susceptible to pediatric exposure than other similar drugs. *See* Indictment ¶ 1.

C. Departments within HHS

The government contends that—aside from the FDA—none of the HHS agencies identified in Indivior’s discovery request and Motion to Compel participated in the investigation of Indivior. *See* Gov. Response at 9-11. In doing so, the government ignores that HHS itself actively participated as a lead member of the investigative team and has knowledge of the activities of its operating divisions, including the Substance Abuse and Mental Health Services Administration (“SAMHSA”), Centers for Disease Control and Prevention (“CDC”), Centers for Medicare and Medicaid Service (“CMS”), National Institutes of Health (“NIH”), and National Institute on Drug Abuse (“NIDA”). As Indivior detailed in its memorandum supporting its Motion to Compel, each of these divisions has analyzed one or more issues that are central to the case and have issued statements indicating they are in possession of documents and information material to Indivior’s defense. *See* Memorandum in Support of Defendants’ Motion to Compel at 9-12 (ECF No. 118) (hereinafter “Indivior Mot. to Compel”).

1. **SAMHSA**

With respect to any such documents and information in SAMHSA's possession, the government again asserts that it has fully complied with its Rule 16 and *Brady* obligations by accessing a single, publicly available document from SAMHSA's website containing statements regarding appropriate buprenorphine dosing amounts. *See* Gov. Response at 9. Armed with knowledge that this SAMHSA publication—which the government readily acknowledges was posted on the SAMHSA website—indicates that “dosing at amounts up to 32 mg per day is recommended for certain patients,”⁵ the government simply downloaded the publication rather than requesting from SAMHSA any documents or information in its possession regarding its analysis of the appropriateness of buprenorphine dosing amounts up to 32 mg for certain patients. Despite the participating agency's clear knowledge of the facts underlying this statement, the government attempts to take a nothing-to-see-here, box-checking approach. This attempt is insufficient to fulfill the government's obligations under Rule 16 and *Brady*, particularly in light of HHS's active involvement in the investigation and knowledge of the work its divisions have performed.

Moreover, while the government suggests that the SAMHSA TIP 40 publication containing this statement is an outlier, Indivior merely cited examples of statements indicating that SAMHSA and other HHS agencies are in the possession of documents and information material to Indivior's defense. *See* Indivior Mot. to Compel at 10. In 2005, SAMHSA issued another publication explaining that while “[m]ost patients are likely to remain stable on 12 to 24

⁵ Substance Abuse & Mental Health Servs. Admin., Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction: A Treatment Improvement Protocol TIP 40, at 8, 55-57 (2004) (hereinafter “TIP 40”).

mg per day, . . . some might need dosages of up to 32 mg per day.”⁶ This publication was reprinted in 2006, 2008, 2010, 2011, 2012, and 2014, and remained available on the SAMHSA website until at least 2017 (at least four years into the government’s investigation of Indivior).⁷ SAMHSA also issued “Federal Guidelines for Opioid Treatment Programs” in 2015, which stated that “[u]nless clinically indicated, there should be no limits on patients’ duration of treatment or dosage level of medication.”⁸ The government is aware of all of these statements and understands that SAMHSA’s analysis of these dosing issues is material to Indivior’s defense. *See, e.g.*, Indictment ¶¶ 14, 20, 97, 99 (addressing buprenorphine dosing amounts higher than 24 mg). The Constitution therefore compels production of such analysis.

2. CDC

The government contends that, aside from the memorandum summarizing its interview with Dr. Daniel Budnitz, who has served as the Director of the Medication Safety Program for the CDC for more than 14 years, the investigative team is not aware of any “additional information residing at CDC.” Gov. Response at 10-11. This position is simply implausible, especially given that memorandum itself indicates that there is additional material in the possession of the CDC that reflects the CDC’s analysis of the impact of unit-dose packing on pediatric exposure. For example, the memorandum indicates that Dr. Budnitz’s study regarding the rates of pediatric emergency room visits, which dropped by two thirds when prescriptions

⁶ Substance Abuse & Mental Health Servs. Admin., Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs: A Treatment Improvement Protocol TIP 43 (2005), at 71.

⁷ *Id.* at ii (“First Printed 2005” and “Reprinted 2006, 2008, 2010, 2011, 2012, and 2014”).

⁸ Substance Abuse & Mental Health Servs. Admin., Federal Guidelines for Opioid Treatment Programs (2015), at 35.

dispensed in unit-dose packaging increased to over 80%,⁹ was based on data from the National Electronic Injury Surveillance System that resides at the CDC.¹⁰ The memorandum also explains that Dr. Budnitz requested that Indivior (then known as RBPI) attend the CDC-sponsored meeting of the Prevention of Overdoses and Treatment Errors in Children Taskforce to explain its decision to move to unit-dose packaging, hoping that “other drug manufacturers would move toward unit-dose packaging in their products to reduce child exposures.”¹¹ Any additional supporting information or documents reflecting Indivior’s participation in this CDC-sponsored meeting and the purpose of that participation, and any data supporting Dr. Budnitz’s observations regarding pediatric exposure in connection with unit-dose packaging are clearly material to Indivior’s defense regarding the alleged falsity of Indivior’s purported statements addressing the safety of Suboxone Film.

3. CMS, NIH, and NIDA

The government further contends that it has no obligation to produce any documents from CMS, NIH, and NIDA because no one from these specific offices participated in the investigation, and because the “efficacy of medication-assisted treatment,” which these agencies have addressed, “is not at issue” in this case. Gov. Response at 11. Again, all of these agencies are divisions of HHS, which actively participated in the investigation of Indivior, and HHS has knowledge of the work being done within its organization. And while the government attempts to discount the materiality of the support for medication-assisted treatment, it has also attempted

⁹ Daniel S. Budnitz, et al., Centers for Disease Control and Prevention, Notes from the Field: Pediatric Emergency Department Visits for Buprenorphine/Naloxone Ingestion—United States, 2008-2015, 65 Morbidity & Mortality Wkly. Rep. 1148 (2016).

¹⁰ Department of Health and Human Services, Office of Inspector General, Report of Interview of Captain Daniel Budnitz, at 3 (Mar. 13, 2019) (M2085-M2089_0000009).

¹¹ *Id.* at 2.

to paint Indivior as a contributor to the opioid epidemic, when in fact Indivior's top priority has always been the treatment of patients struggling with opioid addiction through methods these agencies have supported and labeled "highly underutilized."¹² The documents or other evidence supporting these representations are thus material to Indivior's defense and constitutionally required to be shared with the defense.

III. Indivior has provided ample support to show that any requests for materials from these agencies will produce information and documents subject to disclosure under Rule 16 and *Brady*.

In its Response, the government contends that Indivior's requests are searching and unsupported by facts showing that the requested information will actually help its defense. In fact, Indivior has submitted targeted requests for specific categories of agency information and documents *known* to exist on key issues that undercut the government's theory that Indivior's statements regarding Suboxone Film were false. In short, Indivior has presented far more than a hunch that the requests *may* result in favorable material.

In its brief, the government points to the facts in *United States v. Caro*, 597 F.3d 608, 619 (4th Cir. 2010) and *United States v. Ducore*, 309 F. Supp. 3d 436, 440 (E.D. Va. 2018) to support its argument that Indivior's requests lack necessary support. But each of those cases is readily distinguishable. In both *Caro* and *Ducore*, the defendants could only speculate—without *any* support—"as to what the requested information might reveal." *Caro*, 597 F.3d at 619, 621 ("Caro presented *no facts whatsoever* indicating that the information would have actually helped prove his defense." (emphasis added)); *see also Ducore*, 309 F. Supp. 3d at 440 ("[The]

¹² *See, e.g.*, Nat'l Inst. on Drug Abuse, Medications to Treat Opioid Use Disorder, Research Report Series (2018); Vikki Wachino, Centers for Medicare & Medicaid Services, Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction 14 (2016); Nat'l Inst. on Drug Abuse, Topics in Brief: Medication-Assisted Treatment for Opioid Addiction (2012).

defendant here can only speculate as to the content of the statements of other witnesses on the flight; she has no evidence that the witnesses she seeks to have the government identify would provide any exculpatory information or impeachment evidence.”).

Here, in support of each of its requests, Indivior has provided citations to defense-favorable statements indicating the relevant agency’s conclusions on key issues and/or thorough and supported explanations regarding the agency’s role with respect to the critical oversight of activities tied directly to the charges in the case. In each of these instances, Indivior has also addressed (a) why the known material it has requested will be “favorable to [the] accused,” *Brady v. Maryland*, 373 U.S. 83, 87 (1963), and (b) how the requested evidence is “material to preparing [its] defense,” Fed. R. Crim. P. 16(a)(1)(E)(i); *see also Caro*, 597 F.3d at 621 (“[E]vidence is material as long as there is a strong indication that it will play an important role in uncovering admissible evidence, aiding witness preparation, corroborating testimony, or assisting impeachment or rebuttal.” (alteration in original) (quoting *United States v. Lloyd*, 992 F.2d 348, 351 (D.C. Cir. 1993))).

The government has not provided any support showing that more is required of the defense. Indeed, the application of any higher standard apparently contemplated by the government could never be met. On the one hand, the government argues that Indivior must do more to demonstrate there is particular information in each agency’s possession that would help the defense, but it is the government, and not the defense that has access to the agency information requested. On the other hand, where the government argues that Indivior is in a position to be able to identify particular exculpatory information in the possession of an agency—for example, in the case of Indivior personnel reporting information to the DEA—the

government argues that it need not provide any such information because Indivior “would know of any such report.” *See* Gov. Response at 13.

Considered as a whole, the government’s argument is entirely circular. It suggests it can never be compelled to provide information that is exculpatory or material to the defense because either the defendant already knows about it or, where it lacks all specific details regarding the information, the defendant will be unable to meet the standard of showing how the requested information will help its case. In fact, Indivior has sufficiently established that the investigative team has knowledge of the key information and documents it requests from these agencies and has explained how that information is material to its defense. The obligation therefore rests with the government to comply with Rule 16 and *Brady* and provide these requested materials to Indivior.

IV. Indivior is not asking the government for anything more than what is required under *Brady* and Rule 16.

Finally, in response to Indivior’s request that the Court order the government to identify all exculpatory and impeachment information buried in its multi-million-page production, the government suggests that the company instead spend significant time and resources piecing individually through the millions of pages of documents on its own. *See* Gov. Response at 14. Contrary to the government’s assertion, we are not asking the “United States to review documents for Indivior.” *Id.* Instead, we are simply asking that the government identify the exculpatory documents that it already knows have been produced. *See United States v. Blankenship*, No. 5:14-cr-00244, 2015 WL 3687864, at *7 (S.D. W. Va. June 12, 2015) (concluding that the government, “having determined the nature of the charges and having knowledge of the evidence and witnesses it intends to produce to prove those charges, is in a far better position than the Defendant to know what evidence might be exculpatory and/or

impeachment material under *Brady*”). The fact that a production is searchable or in electronic format matters not when the defendants do not know what they are looking for within the production. Thus, Indivior respectfully requests that the Court require the government to identify by Bates number, or by specific location and title, the information contained within all productions that a reasonable prosecutor would deem exculpatory or impeaching.

CONCLUSION

For the foregoing reasons, and for the reasons addressed in its Memorandum in Support of Defendants’ Motion to Compel, Indivior respectfully requests that this Court grant its Motion to Compel and order the government to produce all Rule 16 and *Brady* material in the possession of the following agencies:

1. Department of Health and Human Services (“HHS”), including
 - a. Centers for Disease Control and Prevention (“CDC”);
 - b. Centers for Medicare and Medicaid Services (“CMS”);
 - c. Food and Drug Administration (“FDA”), including its Office of Prescription Drug Promotion (“OPDP”), formerly known as the Division of Drug Marketing, Advertising, and Communications (“DDMAC”), and its Office of Criminal Investigation (“OCI”);
 - d. National Institutes of Health (“NIH”), including the National Institute on Drug Abuse (“NIDA”); and
 - e. Substance Abuse and Mental Health Services Administration (“SAMHSA”)
2. Drug Enforcement Administration (“DEA”); and
3. Any other federal, state or local agency allied with the prosecution or involved in any way in investigating the activities alleged in the Indictment or related conduct.

The government's production of Rule 16 and *Brady* material, should include, but not be limited to:

- A. Documents or information bearing on the truth or falsity of statements made by Indivior regarding the safety, abuse, misuse, and diversion of Suboxone, including but not limited to any agency reports, studies, and internal communications. This category should include:
 - 1. Documents or information relating to the any agency's assessment of the pediatric safety of buprenorphine products and/or multi-dose versus unit-dose packaging.
 - 2. Documents or information relating to any agency's analysis of the diversion risk associated with buprenorphine products in tablet versus film form or in multi-dose versus unit-dose packaging.
- B. Documents or information bearing on any agency opinion, report, or study regarding appropriate dosages for Suboxone, including but not limited to any documents relating to SAMHSA's statements regarding the appropriateness of Suboxone dosages of up to 32 mg.
- C. Documents or information relating to OPDP / DDMAC's review of Indivior marketing materials containing allegedly false statements.
- D. All DEA and SAMHSA documents or information concerning Doctors A-D and any other health care providers as to whom the government contends Indivior was aware were issuing prescriptions in a "careless and clinically unwarranted" manner, including information regarding when and how the government first became aware of this careless and clinically unwarranted prescribing, any related information from or about the pharmacies filling the prescriptions, and any subsequent investigation of, or disciplinary,

regulatory, or prosecutorial action against, the healthcare provider undertaken in connection with the conduct.

- E. All DEA and SAMHSA documents reflecting information received from Indivior regarding registered and certified (waivered) health care providers.

In addition to the production of the Rule 16 and *Brady* material, Indivior further requests that the Court order the government to identify the exculpatory and impeachment material included in its productions to fulfill its obligations under *Brady*.

Dated: September 27, 2019

Respectfully submitted,

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Pharmaceuticals Inc.) and INDIVIOR PLC

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CERTIFICATE OF SERVICE

I hereby certify that I caused the foregoing to be presented to the Clerk of the Court for filing and uploading to the CM/ECF system, which will send notification of such filing to all counsel of record, on this 27th day of September, 2019.

/s/ Thomas J. Bondurant, Jr. _____

Counsel for Defendants